

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of

FDA DOCKET 2004H-03221

ECUMED HEALTH GROUP,

a corporation,

MOTION FOR ENLARGMENT OF
TIME

and

AMADOR REYES, JUAN C.
CARRAI, RICHARD W. STONE,
M.D., and ERLINDA E. ENRIQUEZ,
M.D.,

Individuals.

ECUMED HEALTH GROUP and AMADOR REYES (collectively "Defendant")
hereby responds to the administrative complaint for civil money damages filed in
the instant matter, and state:

1. No response is required to paragraphs 1, 2, 38, and 39 of the complaint.
2. Defendant admits the allegations contained in paragraph 3, the first sentence of paragraph 4, and paragraphs 5, 6, and 7 of the complaint.
3. Defendant is without knowledge or information sufficient to form a belief as to the allegations contained in paragraphs 8 -37 of the complaint, and, therefore, denies the same and demands strict proof thereof.
4. Any allegation to the complaint not specially addressed herein is denied.

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AFFIRMATIVE DEFENSES

1. Defendant was under the belief that it could continue to perform mammography services while certification issues were being resolved. Thus, FDA is estopped from recovering in these proceedings.

2. The mammography services provided met all requirements of applicable law and thus, there is no rational basis for the institution of this proceeding.


3. Defendant relied on others to ensure that all FDA requirements were met.

4. Defendant has no ability to pay the requested penalty.

WHEREFORE, having answered the complaint, Defendant prays that the complaint be dismissed, that judgment be entered in its favor, that its costs of this action be assessed against plaintiff and for such other and further relief as the Court deems just and proper.

Respectfully submitted this 17th day of September, 2004.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was served via facsimile transmission 301-827-2023 and by U.S. Mail this 17th day of September, 2004 to Michael N. Varrone, Esq., The Center for Devices and Radiological Health, United States Food and Drug Administration, 5600 Fishers Lane (GCF-1), Rockville, MD 20857, and via facsimile 301-827-6870 and by U.S. Mail this 17th day of September, 2004 to Hon. Daniel J. Davidson, Administrative Law Judge, U.S. Food and Drug Administration, Room 9-57, HF-3 5600 Fishers Lane, Rockville, MD 20857, and by U.S. Mail this 17th day of September, 2004 to those listed below.



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